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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/337,619	06/21/1999	ARTHUR M. KREIG	C1039/7021HC	9215

7590

02/26/2002

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EXAMINER

MARTINELL, JAMES

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 02/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/337,619

Applicant(s)

KREIG, ARTHUR M.

Examiner

James Martinell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/7/01, 4/12/01, and 5/21/01.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-98 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-98 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>13</u> . | 6) <input type="checkbox"/> Other: |

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The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1631.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

The substitute paragraph (see the response filed March 7, 2001) for pages 22-23 was not entered because the amendment did not direct entry of same.

The disclosure is objected to because of the following informalities.

- (a) Replacement page 38 (filed with the response of March 7, 2001) is not completely legible. The substitution of a faxed copy of the page in a smaller font than the one used in originally filed page 38 is not an improvement.
- (b) Replacement page 47 (filed with the response of March 7, 2001) is not completely legible. The substitution of a faxed copy of the page in a smaller font than the one used in originally filed page 38 is not an improvement.
- (c) The table on page 23 is not completely legible because some characters are printed on top of others (*e.g.*, see the line beginning "1708").

Appropriate correction is required.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 42-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- (a) The recitation of "increasing the responsiveness" (claim 42) is vague and indefinite, and incomplete. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed October 3, 2000, page 3). Applicants' argument (paper no. 11, pages 8-9) in connection with the use of relative terms

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without a frame of reference is not convincing because it is not implicit that the comparison is to be made to a method that employs no amount of the oligonucleotide. This is especially so in view of the recitation of "an effective amount." Applicants did not argue vagueness and indefiniteness of the term "responsiveness."

- (b) The recitation of "enhancing recovery of bone marrow" (claim 66) is vague and indefinite because the phrase is a relative one with no frame of reference given. This rejection is repeated for reasons already of record (e.g., Office action mailed October 3, 2000, page 4). Applicants' argument (paper no. 11, pages 8-9) in connection with the use of relative terms without a frame of reference is not convincing because it is not implicit that the comparison is to be made to a method that employs no amount of the oligonucleotide

Claims 42-75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for reasons already of record (e.g., Office action mailed October 3, 2000, paragraph bridging pages 4-5). Applicants' arguments (paper no. 11, pages 9-11) and Exhibits 1 (WO 99/58118) and 2 (Wooldrige et al, Blood 89 (8), 2994 (1997)) submitted March 7, 2001 are not convincing. First, applicants do not address the issue of undue experimentation in connection with the lack of guidance in the instant application as to the type of administration, the times or frequencies of administration, or the dosages required to obtain the desired effects. Second, neither one of exhibit 1 nor Exhibit 2 is convincing because applicants do not establish that the materials and methods used in either one of the Exhibits are the same or otherwise comparable to those embraced by the claims.

Claims 76-98 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant

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application gives no data relevant to the use of nucleic acids mentioned in the claims in any *in vivo* method in the treatment or prevention of cancer. One of skill in the art would be compelled to perform undue experimentation in order to practice the claimed invention because of the large number of variables connected with the use of such nucleic acids. For example, the instant application does not give guidance as to the type of administration, the times, or frequencies of administration, or the dosages required to obtain the claimed effects. Additionally, the instant application provides no criteria for the determination of subjects for whom (or which) preventive treatment may be needed. Applicants' arguments (paper no. 11, pages 9-11) and Exhibits 1 (WO 99/58118) and 2 (Wooldrige et al, Blood 89 (8), 2994 (1997)) submitted March 7, 2001 are not convincing. First, applicants do not address the issue of undue experimentation in connection with the lack of guidance in the instant application as to the type of administration, the times or frequencies of administration, or the dosages required to obtain the desired effects. Second, neither one of exhibit 1 nor Exhibit 2 is convincing because applicants do not establish that the materials and methods used in either one of the Exhibits are the same or otherwise comparable to those embraced by the claims. Third, neither of the references shows a method or data for the prevention of a cancer. Finally, the copy of Wooldrige et al is not completely legible.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (703) 308-0296. The fax phone number for Examiner Martinell's desktop workstation is (703) 746-5162. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 305-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


JAMES MARTINELL, Ph.D.
SENIOR LEVEL EXAMINER